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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,056	10/13/1999	ROGER CAROLUS AUGUSTA EMBRECHTS	JAB-1267	6783
7590	03/21/2003			

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

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DATE MAILED: 03/21/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/403,056

Applicant(s)
Embrechts

Examiner
Gollamudi Kishore

Art Unit
1615



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 30, 2003
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 3-15, and 17-23 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-15, and 17-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

The preliminary amendment and the filing under 1.114 dated 1-30-02 are acknowledged.

Claims included in the prosecution are 1, 3-15 and 17--23.

Claim Rejections - 35 U.S.C. § 103

- 1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:**

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 2. Claims 1, 3-15 and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Liu (5,456,851) or Mason (5,536,742) each in combination with either Mayhew (4,209,449) or Fost (5,648,348) or vice versa, i.e., either Mayhew or Fost in combination with either Liu or Mason.**

Liu discloses shampoo formulations containing the various additives and ketonazole as the active ingredient; Liu also discloses that ketonazole is an anti-fungal agent and is useful for the treatment of psoriasis and seborrheic dermatitis (note the abstract, columns 1-4, Examples and claims).

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Mason similarly discloses shampoo preparations containing ketonazole, econazole or miconazole for the treatment of seborrhea. Mason notes the association of this disease with yeast (fungus) (note the abstract, columns 1-2 and claims).

What is lacking in the above references is the inclusion of a phospholipid in the shampoo preparations.

Mayhew while disclosing shampoos, teaches that instant phospholipids exhibit outstanding foaming, viscosity-building, wetting, cleaning, bacteriostatic and other properties (note the abstract, col. 1, line 5 through col. 2, line 8, col. 3, line 53 through col. 5, line 56).

Fost (348) while disclosing various personal care products teaches that the synthetic phospholipids have excellent antifungal activity and well tolerated by human tissues making them suitable for use in personal care products (note the abstract, column 1, lines 10-22, columns 6-7, examples, Example 3 in particular and claims).

The inclusion of a phospholipid in the shampoo compositions of Liu or Mason would have been obvious to one of ordinary skill in the art since the secondary references clearly teach the excellent properties of the phospholipids. Alternately, to include an antifungal agent in the shampoo formulations of Mayhew, or include another antifungal agent would have been obvious to one of ordinary skill in the art since such an inclusion would enable the formulation to treat conditions such as seborrhea and psoriasis as taught

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by Liu or Mason and also one would reasonably expect at least an additive effect of the combination..

3. Claims 1, 3-15 and 17-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Liu (5,456,851) or Mason (5,536,742) each in combination with Mayhew (4,209,449) or Fost (5,648,348) or vice versa, i.e., Mayhew or Fost in combination with either Liu or Mason, as set forth above, in further combination with GB 22 56 139.

The teachings of Liu, Mason, Mayhew and Fost have been discussed above. What is lacking in these references is the combination of the anti-fungal agent and a phospholipid.

GB while disclosing emulsions containing terbinafine and phospholipids, teaches that such a combination results in enhanced efficacy of the compound (note the abstract, page 2, 4 and examples; example 3 in particular).

One of ordinary skill in the art would be motivated further to use phospholipid taught by Mayhew or Fost together with the antifungal compounds of either Liu or Mason, in view of the enhanced efficacy of antifungal agents by phospholipids taught by GB.

Applicant's arguments have been fully considered, but are deemed to be moot in view of the new rejections. The examiner however, would address applicant's pertinent arguments: . Applicant once again argues that Lie, and Mason do not teach phospholipids; the examiner agrees, but points out that the secondary references the use of phospholipids. Applicant argues that given the fact that the compositions of Liu and Mason

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already include an antifungal component, and no suggestion in either Liu or Mason to further include yet another antifungal compound, let alone the particular antifungal phospholipids are Frost. This argument is not found to be persuasive since it is within the skill of the art to include two antifungal agents with a reasonable expectation of obtaining at least an additive effect (see *In re Kerhoven* 205 USPQ 1069). With regard to the synergistic properties argued:- as already pointed out before, a close examination of the results on page 15 of the specification appear to indicate no controls with the antifungal agent or the phospholipids by themselves were performed and no statistical significance of the results has been presented. The examiner points out that scope of the claims is not commensurate with the synergistic effect observed in terms of generic 'antifungal' and phospholipid and in terms of organisms and in terms of amounts of the components.

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is

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more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

March 20, 2003